DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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[Docket No. 02D–0002]

Draft Guidance for Industry on Developing Drugs to Treat Inhalational Anthrax (Post-Exposure); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Inhalational Anthrax (Post-Exposure)—Developing Antimicrobial Drugs." This guidance focuses on the development of antimicrobial drugs for administration to persons who have inhaled aerosolized *Bacillus anthracis*, but who do not yet have the established disease. The treatment goal would be to prevent development of the infection in such persons.

DATES: Submit written or electronic comments on the draft guidance by [*insert date 60 days after date of publication in the* **Federal Register**]. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

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FOR FURTHER INFORMATION CONTACT: Renata Albrecht, Center for Drug Evaluation and Research (HFD–590), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2336.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Inhalational Anthrax (Post-Exposure)—Developing Antimicrobial Drugs." This guidance focuses on the development of antimicrobial drugs for administration to persons who have inhaled aerosolized *B. anthracis*, but who do not yet have the established disease. The treatment goal would be to prevent development of the infection in such persons.

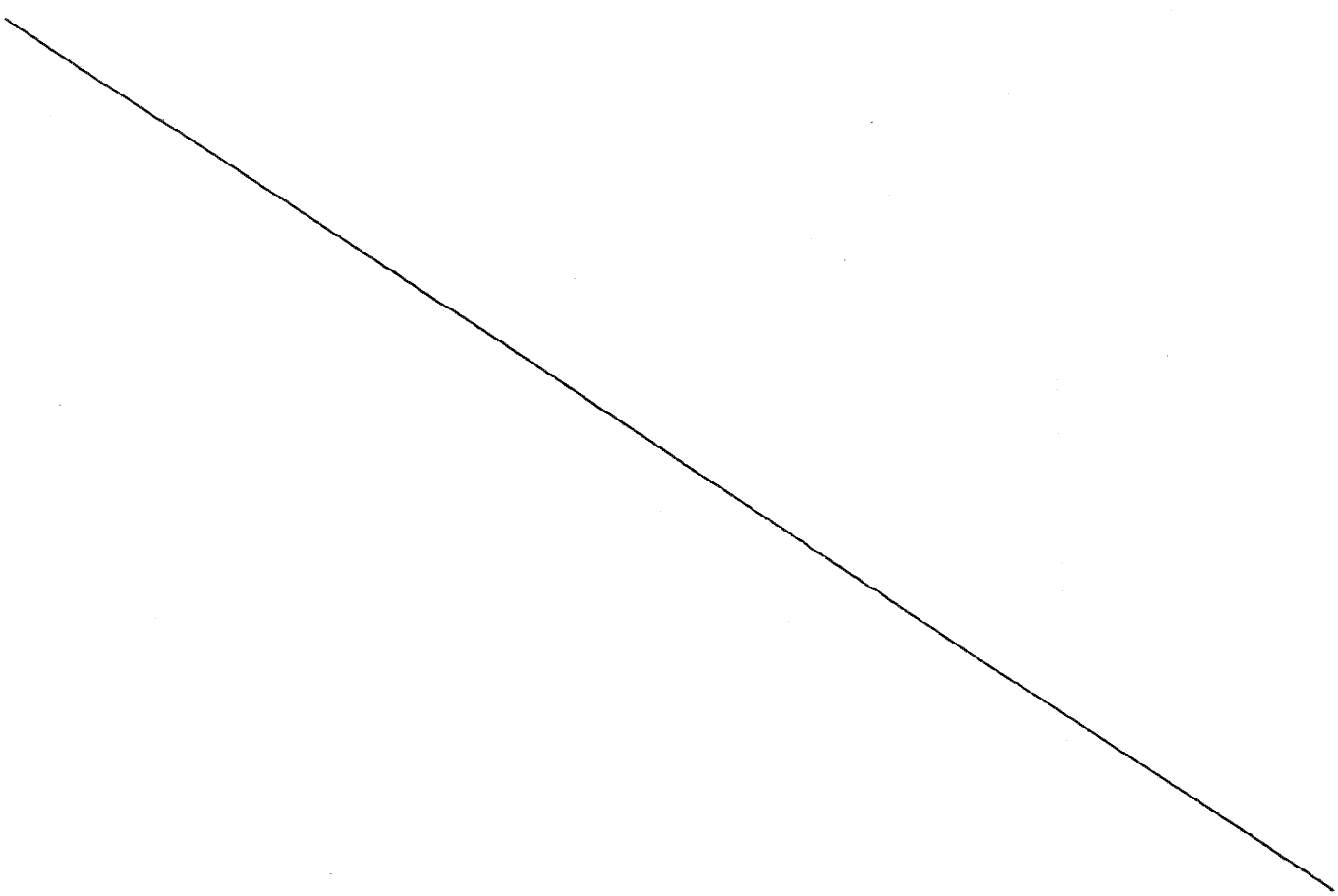
In the fall of 2001, *B. anthracis*, the bacterium that causes anthrax, was used as a bioterrorism agent and sent through the U.S. mail, resulting in cases of cutaneous and inhalational anthrax in New York, New Jersey, the District of Columbia, Florida, and Connecticut. Ciprofloxacin hydrochloride tablets, ciprofloxacin intravenous (IV) solution, ciprofloxacin IV in 5 percent dextrose, ciprofloxacin IV in 0.9 percent saline, and ciprofloxacin oral suspension, which the agency had approved in August 2000 for use in the management of patients who have been exposed to aerosolized spores of *B. anthracis*, were used to treat the potentially infected persons.

Because of the bioterrorism incident, the agency is encouraging the development of additional antimicrobial agents to be used in the event of inhalational exposure to *B. anthracis*. This guidance provides recommendations on how to develop such agents. The guidance is intended to assist applicants who wish to plan, design, conduct, and appropriately monitor the studies, including clinical studies, for drugs to treat persons exposed to *B. anthracis*. Applications submitted to the agency based on studies conducted as recommended in this guidance should yield the information necessary for the agency to determine whether the antimicrobial under study is safe and effective for use in persons exposed to aerosolized *B. anthracis* who do not yet have established disease.

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance represents the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments on the draft guidance by [*insert date 60 days after date of publication in the* **Federal Register**]. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.



III. Electronic Access

Persons with access to the Internet may obtain the document at either http://www.fda.gov/cder/guidance/index.htm or http://www.fda.gov/ohrms/dockets/default.htm.

Dated: 1/14/02

January 14, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

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